The NCI CIRB Initiative is intended to create a more effective and efficient mechanism for IRB oversight of NCI-sponsored Cooperative Group clinical trials. Specifically, by enhancing the protection of study participants by providing consistent expert IRB review at the national level and reducing the administrative burden for local IRBs and research staff.

**Guidance for Local Investigators/Research Team Members to submit new NCI CIRB projects to the HSPPO:**

1. Check NCI CIRB website to ensure the project has NCI CIRB approval and is Group Activated.
2. Ensure that the *Annual Principal Investigator Worksheet About Local Context and Study Specific Worksheet* have been approved by CIRB.
3. Within the UofL ESS, prepare an Initial Submission. In the Application Section “Study Type”, choose "IRB Authorization Agreement".
4. In the Attachments section, upload the following documents:
   Most current documents from the NCI CIRB website:
   - Approval letter
   - NCI CIRB approved full Protocol
   - NCI CIRB approved consent form(s) with local context and HIPAA authorization incorporated
   - Any University compliance committee approval(s), like Institutional Biosafety Committee, if applicable
   - Any local advertising or other recruitment materials, if applicable
   - Local HIPAA document (waiver or partial waiver) that will be used to recruit or screen subjects for this study.
5. Submit study in UofL ESS.
6. Submission received by HSPPO. IRB Analyst/CIRB Liaison adds review outcome of CEDED TO CENTRAL IRB and changes study status to IN REVIEW.
7. University of Louisville IRB/Privacy Board reviews and approves HIPAA document(s) needed and the study status is changed to APPROVED BY CENTRAL IRB.
8. HSPPO issues Deferral Acknowledgment letter to UofL investigator.

**Guidance for submitting local updates to the HSPPO**
Submit amendments for the local study through UofL ESS for:
- PI changes/Study staff changes
- Additional Safety Committee review, if applicable.

**Guidance for Event Reporting to the HSPPO**
Report the following to the HSPPO through UofL ESS:
- Internal UPIRTSOS that are not also AEs or SAEs, for example stolen laptop, security breach.
- Internal events that CIRB determines are UPIRTSOS.
- Internal potential serious or continuing noncompliance.
- Suspensions or terminations of approved research.

**Guidance for closing an NCI CIRB study where NCI CIRB is IRB of Record**
1. Notify the HSPPO of study closure at this site using the UofL ESS by submitting a Amendment-Closure form.
2. Upload the letter from CIRB or the cooperative group indicating that the study is closing at this site.

**HSPPO Auditing for Compliance**
The HSPPO Research Compliance Monitoring Program will include CIRB studies in the routine review program and will review the following:
- Internal potential serious or continuing noncompliance.
- Internal subject complaints.
- All monitoring reports from the UofL site, including those from CIRB cooperative groups, or the FDA.
Guidance for Event Reporting to CIRB
Report the following to CIRB using the *Potential Unanticipated Problem and/or noncompliance* form using IRB Manager on the CIRB website:

- Internal suspected UPIRTSOs that are also AEs or SAEs.
- Internal suspected UPIRRSOs that are not also AEs or SAEs.
- Internal potential serious or continuing noncompliance.

NCI CIRB Auditing for Compliance
Per the IRB Authorization Agreement/Division of Responsibilities, CIRB may conduct audits or consent observations of studies deferred by the University of Louisville to NCI CIRB.

Investigator Responsibilities
1. Initiate research or enroll any subject only after receiving notification from NCI CIRB that the *Study Specific Worksheet about Local Context* has been approved, and the University of Louisville IRB Final Approval letter has been issued.
2. Initiate amendments or changes to an approved protocol only after NCI CIRB review and approval, except where necessary to eliminate apparent immediate hazard to the subject.
3. Changes in PI, study staff, or other changes that may require additional Safety Committee review, must be submitted to the HSPPO prior to implementation.
4. Follow the University of Louisville policies and requirements for conducting research.
5. Conduct the project in accordance with University of Louisville and NCI CIRB policies, federal and state regulations, and cooperative group policies.
6. Notify CIRB and the HSPPO of reportable events as described in this guidance.
7. Submit the *Annual Principal Investigator Worksheet About Local Context* annually for each University of Louisville PI conducting research that is, or will be, deferred to NCI CIRB.
8. Maintain project and regulatory files according to NCI CIRB, federal, and University of Louisville institutional policies.
9. Notify the HSPPO of amendments as described in this policy.
10. Notify the HSPPO of project termination or completion.